Proposed Registration Decision PRD2012-22

Garlic Powder

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Overview

Proposed Registration Decision for Garlic Powder

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Garlic Powder Technical, Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use, containing the technical grade active ingredient garlic powder, to suppress powdery mildew on grape and scab on apple, crabapple, and pear.

Garlic Powder Technical (Registration Number 29666) is fully registered in Canada to suppress powdery mildew on greenhouse food crops (cucumbers and tomatoes). The detailed review for garlic powder can be found in Proposed Regulatory Decision PRD2010-11, *Garlic Powder* and Registration Decision RD2010-11, *Garlic Powder*. Use on terrestrial food crops (grape, apple and pear) and outdoor ornamentals (crab apple) represents major new uses of the active ingredient garlic powder.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Garlic Powder Technical, Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on garlic powder, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on garlic powder, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Garlic Powder?

Garlic powder is the active ingredient in the commercial class end-use products Buran, AEF 11-04, and AEF 11-05. It is also found as the active ingredient in the domestic class end-use products Bioprotec Fruit Tree Fungicide Concentrate and Bioprotec Fruit Tree Fungicide Ready to Use. These products are used to suppress powdery mildew on grape and scab on apple, crabapple, and pear.

Health Considerations

Can Approved Uses of Garlic Powder Affect Human Health?

Garlic powder is unlikely to affect human health when used according to label directions.

Exposure to garlic powder may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The technical grade active ingredient, garlic powder, is of low acute toxicity by the oral and dermal routes and is slightly irritating to eyes and skin. Due to the irritative nature of garlic, inhalation exposure may cause throat irritation. There is potential for skin sensitization to occur when skin is repeatedly exposed to the garlic powder. Therefore, cautionary statements alerting users to this sensitization concern are required on product labels.

Inhalation and dermal exposures are likely for domestic users, occupational workers, and commercial applicators. Anyone entering the sprayed areas before the spray is dried may be exposed dermally. Therefore, appropriate precautionary statements and a restricted entry statement are required on the end-use product labels to mitigate such exposure concerns.

Based on garlic's long history of consumption as a food and in natural health products, there is little indication of short or long term toxic effects from exposure to garlic powder from the use of the commercial and domestic class end-use products.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Garlic is used for culinary purposes world-wide and is also consumed for its medicinal values. Garlic powder is rapidly degraded in the environment, so exposure from residues in water and from treated food commodities is likely to be minimal. There is reasonable certainty that no harmful effects will occur from dietary exposure to garlic powder from the use of the end-use products.

Occupational Risks From Handling Garlic Powder

Occupational risks are not of concern when garlic powder end-use products are used according to label directions, which include protective measures.

As these new products are a liquid formulation, there is no concern from exposure to garlic powder dust during mixing/loading. Occupational exposure when applying the end-use products is not expected to result in unacceptable risk when the end-use product is used according to label directions.

Precautionary and hygiene statements on the label are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Garlic Powder Is Introduced Into the Environment?

Garlic powder technical is not persistent and the proposed use is not expected to pose an unacceptable risk to non-target terrestrial or aquatic organisms.

Garlic powder technical is derived from a naturally-occurring food commodity (garlic bulb). The active components of garlic, allyl sulfides, applied as garlic powder will enter the environment through application by field and airblast sprayer to apple, crabapple, pear and grapes. Allyl sulfides are volatile and, as such, volatilization is expected to be an important route of dissipation for this technical active in the environment. Allyl sulfides are expected to degrade in air by reaction with hydroxyl radicals.

Garlic powder is non-toxic to honey bees and birds and is slightly toxic to fish and aquatic invertebrates on an acute basis. Garlic powder technical will not pose a risk to non-target terrestrial or aquatic organisms from this proposed use.

Value Considerations

What Is the Value of Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use?

Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use are garlic-based preventative fungicides with demonstrated efficacy against powdery mildew and scab.

Powdery mildew on grape and scab on apple, crabapple, and pear are important diseases that can lead to reductions in yield and fruit quality. These products represent valuable low-risk alternative options for disease management available to both commercial and domestic users. The risk of disease resistance development by the target pathogens is assumed to be very low given the general nature of the active ingredient's mode of action.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Buran and AEF 11-04:

In addition to the statement "Avoid breathing spray mists", the labels of the end-use products must include "May cause respiratory irritation." in the Precautions section.

As these products are a liquid formulation, there is no concern from exposure to garlic powder dust during mixing/loading. Therefore, these products have the statement "Applicators using a power sprayer must wear a bayonet-style cartridge respirator (for particulates) equipped with at least an N-95, R-95, P-95 or HE filter."

To avoid bystander exposure, the labels state "Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversion, application equipment and sprayer settings."

In the precautions section, the following statements are included "Individuals who are sensitive or allergic to garlic should avoid handling the product. Individuals who are sensitive or allergic to garlic should avoid treated areas until dry or after a heavy rain."

AEF11-05 and Bioprotec Fruit Tree Fungicide Concentrate

In the precautions section, the end-use product labels state "May cause eye irritation. May cause skin irritation. May cause skin sensitization. May cause respiratory irritation. Avoid breathing spray mists."

In the precautions section, the following statements are included "Individuals who are sensitive or allergic to garlic should avoid handling the product. Individuals who are sensitive or allergic to garlic should avoid treated areas until dry or after a heavy rain."

To avoid bystander exposure, the labels state "Apply only when the potential for drift is minimal."

The statement "KEEP OUT OF REACH OF CHILDREN" is required on the principal display panel.

Bioprotec Fruit Tree Fungicide Ready To Use:

In the precautions section, the end-use product label states "Avoid breathing spray mists."

The statement "KEEP OUT OF REACH OF CHILDREN" is required on the principal display panel.

In the precautions section, the following statements are included "Individuals who are sensitive or allergic to garlic should avoid handling the product. Individuals who are sensitive or allergic to garlic should avoid treated areas until dry or after a heavy rain."

To avoid bystander exposure, the label states "Apply only when the potential for drift is minimal."

Next Steps

Before making a final registration decision on garlic powder, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on garlic powder (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Garlic Powder

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Garlic
Function	
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	N/A
2. Chemical Abstracts Service (CAS)	N/A
CAS number	N/A
Molecular formula	N/A
Molecular weight	N/A
Structural formula	N/A
Purity of the active ingredient	100%

1.2 Physical and Chemical Properties of the Active Ingredients and End-use Product

Technical Product—Garlic Powder Technical

Property	Result
Colour and physical state	White-yellow powder
Odour	Slight garlic odour
Melting range	N/A (mixture of various compounds)
Boiling point or range	N/A (the product is solid)
Density	0.33–0.35 g/cm^3
Vapour pressure at 20°C	N/A
Henry's law constant at 20°C	N/A
Ultraviolet (UV)-visible spectrum	N/A
Solubility in water at 20°C	40 g/L

Property	Result
Solubility in organic solvents at 20°C (g/100 mL)	N/A
n-Octanol–water partition coefficient (K_{ow})	N/A
Dissociation constant (pK_a)	N/A
Stability (temperature, metal)	N/A

End-use Product—Buran

Property	Result
Colour	Brown
Odour	Garlic odour
Physical state	Liquid
Formulation type	Solution (SN)
Guarantee	15%
Container material and description	HDPE plastic drums (10 to 205 L) Fibre drums, plastic HDPE – PTE – PE - PP
Density	1.03–1.08 g/cm^3
pH	7.0–8.0
Oxidizing or reducing action	The product is not expected to be a reducing or oxidizing agent
Storage stability	The product is expected to be stable for 12 months when stored in commercial packaging.
Corrosion characteristics	The product is not expected to be corrosive.
Explodability	The product is not expected to be explosive.

End-use Product—AEF 11-04

Property	Result
Colour	Brown
Odour	Garlic odour
Physical state	Liquid
Formulation type	Solution (SN)
Guarantee	30%
Container material and description	HDPE plastic drums (10 to 205 L) Fibre drums, plastic HDPE – PTE – PE - PP
Density	1.02–1.08 g/m^3

Property	Result
pH	7.0–8.0
Oxidizing or reducing action	The product is not expected to be a reducing or oxidizing agent
Storage stability	The product is expected to be stable for 12 months when stored in commercial packaging.
Corrosion characteristics	Not expected to be corrosive
Explodability	The product is not expected to be explosive.

End-use Product—AEF 11-05

Property	Result
Colour	Brown
Odour	Garlic odour
Physical state	Liquid
Formulation type	Solution (SN)
Guarantee	30%
Container material and description	HDPE plastic drums (0.2 to 4.0 L) HDPE – PTE – PE - PP
Density	1.03–1.08 g/cm^3
pH	7.0–8.0
Oxidizing or reducing action	The product is not a reducing or oxidizing agent
Storage stability	The product is expected to be stable for 12 months when stored in commercial packaging
Corrosion characteristics	Not expected to be corrosive.
Explodability	The product is not expected to be explosive.

End-use Product—Bioprotec Fruit Tree Fungicide Concentrate

Property	Result
Colour	Brown
Odour	Garlic odour
Physical state	Liquid
Formulation type	Solution (SN)
Guarantee	15%
Container material and description	HDPE plastic drums (0.2 to 4.0 L) HDPE – PTE – PE - PP
Density	1.03–1.08 g/cm^3
pH	7.0–8.0

Property	Result
Oxidizing or reducing action	The product is not expected to be a reducing or oxidizing agent
Storage stability	The product is expected to be stable for 12 months when stored in commercial packaging.
Corrosion characteristics	Not expected to be corrosive.
Explodability	The product is not expected to be explosive.

End-use Product—Bioprotec Fruit Tree Fungicide Ready to Use

Property	Result
Colour	Brown
Odour	Garlic odour
Physical state	Liquid
Formulation type	Solution (SN)
Guarantee	0.108%
Container material and description	HDPE plastic drums (0.5 to 4.0 L) Fibre drums, plastic HDPE – PTE – PE - PP
Density	1.02–1.08 g/cm^3
pH	7.0–8.0
Oxidizing or reducing action	The product is not expected to be a reducing or oxidizing agent
Storage stability	The product is expected to be stable for 12 months when stored in commercial packaging.
Corrosion characteristics	Not expected to be corrosive
Explodability	The product is not expected to be explosive.

1.3 Directions for Use

Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use are used for the suppression of powdery mildew on grape (including ornamental grapevine) and scab on apple, crabapple, and pear. The proposed use pattern for each claim on the five end-use product labels all result in comparable application rates in terms of active ingredient, i.e. 1.1 g a.i./ 4 m^2 or 2.7 kg a.i./ha. All treatments are intended as preventative foliar applications.

1.4 Mode of Action

Many details of the fungicidal mode of action of garlic powder remain to be determined; however, the active ingredient has been demonstrated to cause loss of turgor in target pathogen cells and a general collapse of hyphae and spores.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

Based on the nature of the product, this requirement is waived.

2.2 Method for Formulation Analysis

Based on the nature of the product, this requirement is waived.

2.3 Methods for Residue Analysis

Methods for residue analysis were not required.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Refer to Proposed Regulatory Decision PRD2010-11, *Garlic Powder* and Registration Decision RD2010-11, *Garlic Powder* for a toxicology summary of the active ingredient, garlic powder.

Garlic powder is of low acute toxicity by the oral and dermal routes and is slightly irritating to eyes and skin. Inhalation exposure to garlic powder is likely to cause irritation of the respiratory tract and may result in allergic reaction.

3.2 Occupational, Residential and Bystander Exposure and Risk Assessment

3.2.1 Use Description /Exposure Scenario

The commercial use of Buran and AEF 11-04 is as a foliar spray on grapevines to suppress powdery mildew and on apple, crabapple and pear trees to suppress scab. The application rate of Buran is 18 L/ha, which is equivalent to 2.7 kg a.i./ha, in a spray volume between 250-1000 L/ha. The application rate of AEF 11-04 is 9 L/ha, which is equivalent to 2.7 kg a.i./ha, in a spray volume between 250-1000 L/ha. Application is recommended every 7 to 14 days depending on the disease incidence. The products are to be applied by standard backpack or airblast sprayer by professional pesticide field applicators. On average, an applicator can treat 10 ha of field in a day with 27 kg active ingredient. It is recommended to fill the mixing tank or sprayer with a certain amount of clean water before adding Buran or AEF 11-04 to avoid settling. Constant agitation is required to maintain suspension of the solution.

The domestic uses of AEF 11-05 and Bioprotec Fruit Tree Fungicide Concentrate are as foliar sprays on grapevines (including ornamental) to suppress powdery mildew and on apple, crabapple and pear trees to suppress scab. The application rate of AEF 11-05 will be 3.6 mL in 400 mL to 1 L of clean water to cover 4 sq. meter of foliage, which is equivalent to 9 L/hectare.

The application rate of Bioprotec Fruit Tree Fungicide Concentrate will be 7.2 mL in 400 mL to 1 L of clean water to cover 4 m^2 of foliage, which is equivalent to 18 L/hectare. The products should have thorough coverage of the target foliage but not to the point of excessive run-off. Application is recommended every 7 to 14 days according to economic threshold and disease incidence. The products are to be applied by small backpack or hand held sprayer by domestic users. It is expected that the applicator will handle 1.08 g active ingredient per 4 sq. metres. Constant agitation is required to maintain suspension of the solution.

The domestic use of Bioprotec Fruit Tree Fungicide Ready To Use is as a foliar spray on grapevines (including ornamental) to suppress powdery mildew and on apple, crabapple and pear trees to suppress scab. Bioprotec Fruit Tree Fungicide Ready To Use is a 1 L ready-to-use product using a hand held sprayer which will cover 4 m^2 of foliage. The product should have thorough coverage of the target foliage but not to the point of excessive run-off. Application is recommended every 7 to 14 days according to economic threshold and disease incidence. It is expected that the applicator will handle 1.08 g active ingredient per 4 m^2. Constant agitation is required to maintain suspension of the solution.

3.2.2 Mixer, Loader and Applicator Exposure and Risk Assessment

For Buran and AEF 11-04, occupational exposure to the end-use product will be minimal if workers follow label recommendations. The label has a number of exposure reduction statements (for example, personal protective equipment, clothing, hygiene statement) to protect workers against any unnecessary risk from exposure. When handling, loading, mixing, and/or applying the end-use product, and during clean-up/maintenance activities, workers should wear a long-sleeved shirt and pants, water-proof gloves, eye goggles, shoes, and socks. Also, the Buran and AEF 11-04 labels state that individuals avoid contact of spray solution with skin, eyes or clothing, avoid breathing spray mists, and the handling and loading of the end-use product, as well as the clean-up and maintenance activities to be performed in a well-ventilated area. As these products are a liquid formulation, there is no concern from exposure to garlic powder dust during mixing/loading. PMRA requires that "Applicators using a power sprayer must wear a bayonet-style cartridge respirator (for particulates) equipped with at least an N-95, R-95, P-95 or HE filter." In addition, PMRA requires "Individuals who are sensitive or allergic to garlic should avoid handling the product."

Significant risk from exposure to Buran and AEF 11-04 for the mixer, loader, and applicator, as well as those responsible for clean-up and maintenance activities is not anticipated, due to the low toxicity of the end-use product and reduced occupational exposure when label directions are followed.

For AEF 11-05 and Bioprotec Fruit Tree Fungicide Concentrate, residential exposure to the end-use product will be minimal if domestic users follow label recommendations. The label has a number of exposure reduction statements (for example, precautionary and hygiene statements) to protect domestic users. When handling, mixing, loading, and/or applying the end-use product, and during clean-up/maintenance activities individuals should wear a long sleeved shirt, long pants, waterproof gloves and eye goggles. Also, the AEF 11-05 and Bioprotec Fruit Tree

Fungicide Concentrate labels state that individuals avoid contact of spray solution with skin, eyes or clothing. It is recommended to avoid breathing spray mists. The labels also state to wash thoroughly with soap and water after handling and to remove contaminated clothing and wash before re-use. Individuals who are sensitive or allergic to garlic should avoid handling the product, as well as, avoid treated areas until dry or after a heavy rain.

Significant risk from exposure to AEF 11-05 and Bioprotec Fruit Tree Fungicide Concentrate for the mixer, loader, and applicator, as well as those responsible for clean-up and maintenance activities is not anticipated, due to the low toxicity of the end-use product and reduced occupational exposure when label directions are followed.

For Bioprotec Fruit Tree Fungicide Ready To Use, residential exposure to the end-use product will be minimal if homeowners follow label recommendations. The label has a number of exposure reduction statements (for example, precautionary and hygiene statements) to protect domestic users. As the ready-to-use end-use product is packaged in spray bottles, there will be no mixing or loading. When handling or applying the end-use product, and during clean-up/maintenance activities, the Bioprotec Fruit Tree Fungicide Ready To Use label states that individuals avoid contact of spray solution with skin, eyes or clothing. It is recommended to avoid breathing spray mists. The label also states to wash thoroughly with soap and water after handling and to remove contaminated clothing and wash before re-use. Individuals who are sensitive or allergic to garlic should avoid handling the product, as well as, avoid treated areas until dry or after a heavy rain.

Significant risk from exposure to Bioprotec Fruit Tree Fungicide Ready To Use for the applicator is not anticipated due to the low toxicity of the end-use product and reduced occupational exposure when label directions are followed.

3.2.3 Bystander Exposure and Risk Assessment

For Buran and AEF 11-04, bystander exposure is expected to be low because the product label states that unprotected persons should be kept out of the treated areas for the duration of the treatment period. In addition, PMRA requires adding the following statements under the Precautions section: "Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversion, application equipment and sprayer settings" and "Individuals who are sensitive or allergic to garlic should avoid treated areas until dry or after a heavy rain."

For AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate and Bioprotec Fruit Tree Fungicide Ready To Use, bystander exposure is expected to be low when domestic users follow the label directions such as applying the product when the potential for drift is minimal.

3.2.4 Postapplication Exposure

For Buran and AEF 11-04, there are no postapplication activities associated with the end-use product. To prevent postapplication dermal exposure from wet surfaces, restricting entry until the spray is dried for workers/individuals following the end-use product application is required on the end-use product label.

For AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate and Bioprotec Fruit Tree Fungicide Ready To Use, there are no postapplication activities associated with the end-use product. Due to the potential for an allergic reaction in individuals sensitive to garlic, appropriate precautionary label statements are required on the label. Individuals who are sensitive or allergic to garlic should avoid treated areas until dry or after a heavy rain.

3.3 Food Residues Exposure Assessment

Garlic powder can be considered to be non-persistent in the environment based on the knowledge of its composition; for example, organic material known to be rapidly degraded by biological, physical, and /or chemical processes to elemental constituents following the pesticide application; therefore, human exposure to biologically active pesticidal residues from treated crops is expected to be minimal. Furthermore, washing treated produce before human consumption will further reduce pesticide residue intake. Garlic powder is primarily used world-wide as a food additive or food component, has a long history of safe consumption, and is valued for its benefits to human health.

In the United States, garlic is classified by the Food and Drug Administration as generally recognized as safe (GRAS). It is exempt from the requirement of a food tolerance as an active or inert ingredient because it is considered a commonly consumed food commodity under 40CFR 180.950(a).

There is reasonable certainty that no harmful effects will result from dietary exposure to residues of the end-use products based on the low levels of toxicity, the long history of safe consumption of garlic and the low potential for exposure. Levels of exposure resulting from use of the commercial and domestic end-use products would be significantly lower than those found in the population's consumption of garlic-based foods (raw, cooked and processed). Consequently, the PMRA has not required the establishment of a maximum residue limit (MRL) for garlic powder.

4.0 Impact on the Environment

Garlic powder has a low toxicity profile and long history of use and, as such, was evaluated following the approach outlined in Regulatory Directive DIR2012-01, *Guidelines for the Registration of Non-Conventional Pest Control Products*. Therefore, a reduced database of acute toxicity information was deemed sufficient to characterize the potential risks to the environment from the use of Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use.

4.1 Fate and Behaviour in the Environment

Information on the active components of garlic, allyl sulfides, was used to describe the fate and behaviour of this technical active ingredient (see Appendix I, Table 1). Garlic powder is soluble in water whereas allyl sulfides are reported to be practically insoluble. Allyl sulfides are volatile (Henry's law constant of 1.3×10^{-3} atm.m^{-3}/mole; vapor pressure of 9.22 mm Hg at 25°C) and are expected to volatilize from plant, soil, and water surfaces followed by rapid degradation in the environment through interaction with photochemically-produced hydroxyl radicals. Hydrolysis and photolysis of allyl sulfides are not important processes. An estimated log K_{ow} of 2.6 suggests a low potential for bioaccumulation. Cultivated and wild garlic (*Allium* sp.) naturally release measurable concentrations of allyl sulfides to the environment (i.e. air) during growth. In general, garlic powder technical and allyl sulfides will not persist in the environment.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the maximum application rates(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by the toxicity value (i.e. endpoint) which has had the appropriate species uncertainty factor applied (RQ = exposure/toxicity endpoint). The risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

A summary of toxicity data for terrestrial organisms is in Appendix I, Table 2.

The potential exposure of garlic powder to honey bees was assessed for the proposed orchard and vineyard uses. The maximum seasonal rate was calculated using a foliar half-life of one day (based on information that the active substances in garlic powder, allyl sulfides, will volatilize quickly from plant surfaces) and 10 applications spaced seven days apart. The LD_{50} for bees was converted to an equivalent value in kg a.i./ha (UF, uncertainty factor = 1) resulting in an RQ <0.1 (Appendix I, Table 3). The LOC for honeybees was not exceeded.

The potential exposure of garlic powder to birds was assessed based on screening level estimated daily exposure values (EDEs) from food items sprayed with the maximum seasonal application rate (2.7 kg a.i./ha) for the proposed orchard and vineyard uses. The maximum seasonal rate was calculated using a foliar half-life of one day (as for honeybees) and 10 applications spaced seven days apart. The acute oral LD_{50} for northern bobwhite quail (UF = 10) resulted in an RQ value <0.68 (Appendix I, Table 4). The LOC for birds was not exceeded.

Based on the overall low toxicity profile of garlic powder, and a long history of use as a food substance, no adverse effects are anticipated to small mammals from the use of Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use.

4.2.2 Risks to Aquatic Organisms

A summary of toxicity data for aquatic organisms is in Appendix I, Table 2.

For fish, *Daphnia* and amphibians, the potential exposure of garlic powder to the aquatic environment was assessed based on screening level estimated environmental concentrations (EECs) from an application of garlic powder to water bodies of two different depths (80 cm and 15 cm), 10 applications at a proposed maximum single application rate of 2.7 kg a.i./ha, a seven day application interval and a conservative aerobic water half-life of four days. The 80-cm depth was chosen to represent a permanent body of water and the 15 cm depth was chosen to represent a seasonal body of water. The risk to aquatic life-stages of amphibians was assessed by comparing EECs in 15 cm water depth with fish toxicity values as surrogate endpoints. The screening level risk assessment indicated that the LOC was not exceeded for acute exposure of garlic powder to *Daphnia* (RQ = 0.03; UF = 2), fish (RQ = 0.14; UF = 10) or amphibians (RQ = 0.78; UF=10) (Appendix I, Table 3).

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

5.1.1.1 Suppression of scab on apple, crabapple, and pear

In a series of three field trials, applications of comparable garlic powder-based products were shown to provide significant protection against scab in apple. With the number of sprays ranging from six to nine and an application rate equivalent or close to the proposed 2.5 kg of active ingredient per hectare, the trial conditions were representative of those resulting from the labelled use directions. Significant reductions in disease control were observed in all three trials reaching up to 88%. Additional evidence of the active ingredient's effect was obtained from in vitro experiments that showed garlic powder inhibiting hyphal growth in the scab-causing pathogen.

All of the field trial evidence was obtained from apple trees. However, because of the close biological similarities among the crops in question and between the two pathogen species that cause scab in pome fruits, this evidence can be extrapolated to support the claim of suppression of scab on crabapple and pear.

5.1.1.2 Suppression of powdery mildew on grape

Evidence demonstrating the effectiveness of the garlic powder products against grape powdery mildew is derived from three field trials conducted on grapevines in Quebec and British Columbia. Significant reductions of disease severity and incidence attributable to garlic powder applications were observed in all three trials. Reductions in disease incidence of up to 82% were observed in leaves when a comparable garlic-based product was included in a spray program. These trials were conducted under low to high disease pressure and disease assessments were made on shoots, leaves and fruits. The use patterns employed in the trials were similar to those proposed on the five product labels in that treatments with applications rates close or equal to 2.5 kg of active ingredient per hectare were included.

5.2 Phytotoxicity

Phytotoxicity was assessed in each of the grape and apple trials. No adverse effects resulting from the various applications of the garlic powder products were reported.

5.3 Economics

Not assessed.

5.4 Sustainability

5.4.1 Survey of Alternatives

The chemical and other non-conventional/biological fungicidal active ingredients listed in Appendix I, Table 5 are found in products that are registered for suppression of the diseases appearing on the labels for Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use (i.e. grape powdery mildew or scab on apple, crab apple, or pear).

5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

Possible adverse effects of the concurrent use of conventional pesticides on garlic powder efficacy have not been extensively tested. However, trials on grape powdery mildew where garlic powder-based products were included in a spray program with standard chemical products showed good efficacy. These results support the idea that Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use are compatible with current conventional disease management practices. None of the elements of the labelled use patterns would reasonably be expected to interfere with or be impacted by standard disease management practices including integrated pest management.

5.4.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Garlic powder, the active ingredient in Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use, is a non-conventional biological fungicide with a general multi-site mode of action. Consequently, development of disease resistance to garlic powder fungicidal activity is not expected. No reports of possible disease resistance are known at this time.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, garlic powder was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Garlic powder is not expected to be persistent or bioaccumulative (estimated log K_{ow} = 2.6 for allyl sulfide). Therefore, garlic powder technical does not meet Track 1 criteria and is not considered a Track 1 substance.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade garlic powder and the associated end-use products do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

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5 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

7.0 Summary

7.1 Human Health and Safety

The available information for garlic powder is adequate to qualitatively identify the toxicological hazards that may result from human exposure to garlic powder. Garlic powder is of low acute toxicity by oral and dermal routes. It is slightly irritating to skin and eyes, but is a potential skin sensitizer. Repeated dermal exposure to garlic powder in the commercial and domestic end-use products can result in skin sensitization. Due to the irritative nature of garlic powder, inhalation exposure is likely to cause irritation of the respiratory tract.

Occupational and residential exposure to the commercial and domestic end-use products are expected to be minimal if the precautionary statements and required personal protective equipment on the product label, which are intended to minimize worker exposure, are observed. Bystander exposure is likely to be negligible to nonexistent. Postapplication exposure can be minimized by restricted entry.

The dietary risk due to exposure to garlic powder from the use of the proposed end-use product is considered negligible. The PMRA did not establish maximum residue limit (MRL) for garlic powder.

7.2 Environmental Risk

Garlic powder technical is derived from a naturally-occurring food commodity (garlic bulb). Garlic powder and its active components (allyl sulfides) are expected to dissipate rapidly in the environment and degrade through reactions with photochemically produced hydroxyl radicals. The proposed use of garlic powder technical is not expected to pose unacceptable risks to non-target terrestrial and aquatic organisms.

7.3 Value

Buran, AEF 11-04 and AEF 11-05 are non-conventional products that represent an option to commercial growers looking to avoid or reduce the use of conventional chemical fungicides to manage important diseases in grape, apple, crabapple, and pear. These products will be of particular value to organic producers who have limited options available to manage economically important diseases such as powdery mildew and scab. Bioprotec Fruit Tree Fungicide Concentrate and Bioprotec Fruit Tree Fungicide Ready to Use will provide similar advantages to domestic users.

7.4 Unsupported Uses

Not applicable as all uses were supported (Appendix 1, Table 6).

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Garlic Powder Technical, Buran, AEF 11-04, AEF 11-05, Bioprotec Fruit Tree Fungicide Concentrate, and Bioprotec Fruit Tree Fungicide Ready to Use, containing the technical grade active ingredient garlic powder, to suppress powdery mildew on grape and scab on apple, crab apple, and pear.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	microgram(s)
µL	microliter(s)
a.i.	active ingredient
atm	atmosphere
bw	body weight
°C	degree(s) celcius
CAS	Chemical Abstracts Service
cm^3	centimetre(s) cubed
EDE	estimated daily exposure
EEC	estimated environmental concentration
g	gram(s)
ha	hectare(s)
HDPE	high density polyethylene
Hg	mercury
hr	hour(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
m^2	metre(s) squared
m^3	metre(s) cubed
mg	milligram(s)
mL	millilitre(s)
mm	millimetre(s)
MRL	maximum residue limit
N/A	not applicable
nm	nanometre(s)
PE	polyethylene
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PP	polypropylene
ppm	parts per million
PTE	polyethylene terephthalate
RQ	risk quotient
SN	solution
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Fate and Behaviour of Garlic Powder Technical and Ally Sulfides

Property	Substance	Value / Comments
Solubility in water (g/L)	Garlic powder technical Allyl sulfides	40 Practically non-soluble
Vapour pressure (@ 25°C)	Allyl sulfides	9.22 mm Hg
Henry's law constant ($atm.m^3$/mole)		$1.3 \times 10^{E-3}$
Log K_{ow} (estimated)		2.6
K_{oc} (estimated)		270
Estimated volatilization half-life		Model river system: 4 hours
		Model lake system: 4 days
Atmospheric half-life (hours)		Hydroxyl radicals: 5 hours
		Ozone: 11 hours
Hydrolysis		Not expected; no hydrolysable groups
Photolysis		Does not contain chromophores that absorb light at wavelengths >290 nm

Table 2 Toxicity to Non-Target Species

Organism	Exposure	Endpoint	Degree of toxicity[a]	PMRA #
Honey bees (*Apis mellifera*)	48hr-acute contact	LD_{50} >25 µg a.i./bee	practically non toxic	1604000
Northern Bobwhite Quail (*Colinus virginianus*)	Acute oral	LD_{50} > 2000 mg a.i./kg bw	practically non-toxic	1604004
	5-day acute dietary	LD_{50}> 1097 mg a.i./kg bw/day	practically non-toxic	1691838
Water flea *(Daphnia magna)*	48-hr-acute	LC_{50}: 33.24 mg a.i./L	slightly toxic	1603998
Rainbow trout (*Oncorhynchus mykiss)*	96-hr acute	LC_{50} : 32.88 mg a.i./L	slightly toxic	1604002

[a] USEPA classification

Table 3 Screening Level Risk Assessment of Garlic Powder on Non-target Species (Other Than Birds and Mammals)

Organism	Exposure	Endpoint value (divided by uncertainty factor)	EEC	RQ	Level of concern exceeded?
Honey bee (*Apis mellifera*)	48hr-acute contact	LD_{50} /1 >28 kg a.i./ha*	2.7 kg a.i./ha	<0.1	No
Water flea *(Daphnia magna)*	48-hr-acute	LC_{50}/2: 16.6 mg a.i./L	0.48 mg a.i./L	0.03	No
Rainbow trout (*Oncorhynchus mykiss)*	96-hr acute	LC_{50}/10: 3.3 mg a.i.L	0.48 mg a.i./L	0.14	No
Amphibians	Acute	LC_{50}/10: 3.3 mg a.i./L	2.56 mg a.i./L	0.78	No

* According to Atkins *et al.* (1981), the LD_{50} in micrograms a.i. per bee (µg a.i./bee) can be converted to the equivalent application rate in kg/ha by multiplying µg/bee by 1.12.

Table 4 Screening level risk assessement of garlic powder for birds

	Toxicity* (mg ai/kg bw/day)	Feeding Guild (food item)	EDE (mg ai/kg bw)[a]	RQ	Level of concern exceeded
Small Bird (0.02 kg)					
Acute	>200.00	Insectivore (small insects)	136.05	<0.68	No
Medium Sized Bird (0.1 kg)					
Acute	>200.00	Insectivore (small insects)	106.17	<0.53	No
Large Sized Bird (1 kg)					
Acute	>200.00	Herbivore (short grass)	110.78	<0.55	No

[a] EDE = Estimated daily exposure; is calculated using the following formula: (FIR/BW) x EEC, where:

FIR: Food Ingestion Rate (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:

Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = $0.398(BW \text{ in g})^{0.850}$

All birds Equation (body weight > 200 g): FIR (g dry weight/day) = $0.648(BW \text{ in g})^{0.651}$.

BW: Generic Body Weight

EEC: Concentration of pesticide on food item based on Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher et al. (1994). At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used.

*LD_{50}/uncertainity factor of 10.

Table 5 Alternative Fungicides Registered for Powdery Mildew on Grape and Scab on Apple, Crab Apple, and Pear

Pests	Crop	Active Ingredient (Resistance Management Group)
Powdery mildew	Grape	*Bacillus subtilis* QST 713 (44)
		Boscalid (7)
		Calcium polysulfide (M2)
		Copper oxychloride (M2)
		Difenoconazole (3)
		Folpet (M4)
		Kresoxim-methyl (11)
		Metrafenone (U8)
		Myclobutanil (3)
		Potassium bicarbonate (NC)
		Pyraclostrobin (11) + boscalid (7)
		Quinoxyfen (13)
		Sulphur (M2)
		Trifloxystrobin (11)
Scab	Apple, crab apple, and pear	Bacillus subtilis QST 713 (44)[abc]
		Boscalid (7) + pyraclostrobin (11)[abc]
		Calcium polysulphide (M2)[ab]
		Captan (M4)[ab]
		Chlorothalonil (M5)[c]
		Cyprodinil (9)[b]
		Difenoconazole (3)[abc]
		Dodine (U12)[ab]
		Ferbam (M3)[ab]
		Fluazinam (29)[b]

Pests	Crop	Active Ingredient (Resistance Management Group)
		Flusilazole (3)[b]
		Folpet (M4)[bc]
		Kresoxim-Methyl (11)[ab]
		Mancozeb (M3) + Dinocap (29)[ab]
		Mancozeb (M3)[b]
		Mancozeb (M3) + myclobutanil (3)[b]
		Metiram (M2)[b]
		Myclobutanil (3)[abc]
		Penthiopyrad (7)[abc]
		Propiconazole (3)[c]
		Pyrimethanil (9)[ab]
		Sulphur (M2)[ab]
		Thiophanate-methyl (1)[ab]
		Thiram (M3)[b]
		Trifloxystrobin (11)[abc]
		Ziram (M3)[b]

[a] registered for use on pear
[b] registered for use on apple
[c] registered for use on crab apple

Table 6 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Proposed use claim	Supported Use
To suppress powdery mildew (*Erysiphe necator*) on grapevine, apply: • **Brusan** at 18 L/ha, • **AEF 11-04** at 9 L/ha, • **AEF 11-05** at 3.6 mL/4 m^2, • **Bioprotec Fruit Tree Fungicide Concentrate** at 7.2 mL/4 m^2 • or **Bioprotec Fruit Tree Fungicide Ready to Use** at 1 L/4 m^2. Ensure thorough coverage.	Supported as proposed
To suppress scab (*Venturia inaequalis*, and *V. pirina*) on apple, crab apple, and pear, apply: • **Brusan** at 18 L/ha, • **AEF 11-04** at 9 L/ha, • **AEF 11-05** at 3.6 mL/4 m^2, • **Bioprotec Fruit Tree Fungicide Concentrate** at 7.2 mL/4 m^2 • or **Bioprotec Fruit Tree Fungicide Ready to Use** at 1 L/4 m^2. Ensure thorough coverage.	Supported as proposed

References

A. List of Studies/Information Submitted by Registrant

Chemistry

PMRA Document Number	Reference
2049254	2011, Chemistry requirements for TGAI, DACO: 2.1, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.13.1, 2.13.2, 2.13.3, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
2040680	2011, Chemistry requirements for EP, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
2040681	2011, Manufacturing process, DACO: 3.2.1, 3.2.2, 3.2.3 CBI
2040682	2011, Specifications, DACO: 3.3.1, 3.3.2 CBI
2040684	2011, Product analysis, DACO: 3.4.1, 3.4.2 CBI
2040685	2011, Chemical and physical properties, DACO: 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2040686	2011, Storage stability, DACO: 3.5.10 CBI
2040687	2011, Storage stability, DACO: 3.5.10 CBI
2040753	2011, Chemistry requirements for EP, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
2040755	2011, Manufacturing process, DACO: 3.2.1, 3.2.2, 3.2.3 CBI
2040756	2011, Specifications, DACO: 3.3.1, 3.3.2 CBI
2040758	2011, Product analysis, DACO: 3.4.1, 3.4.2 CBI
2040759	2011, Chemical and physical properties, DACO: 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2040760	2011, Storage stability, DACO: 3.5.10 CBI
2040761	2011, Storage stability, DACO: 3.5.10 CBI
2040786	2011, Chemistry requirements for EP, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
2040787	2011, Manufacturing process, DACO: 3.2.1, 3.2.2, 3.2.3 CBI

2040788 2011, Specifications, DACO: 3.3.1, 3.3.2 CBI

2040790 2011, Product analysis, DACO: 3.4.1, 3.4.2 CBI

2040791 2011, Chemical and physical properties, DACO: 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI

2040792 2011, Storage stability, DACO: 3.5.10 CBI

2040793 2011, Storage stability, DACO: 3.5.10 CBI

2040833 2011, Chemistry requirements for EP, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI

2040835 2011, Manufacturing process, DACO: 3.2.1, 3.2.2, 3.2.3 CBI

2040836 2011, Specifications, DACO: 3.3.1, 3.3.2 CBI

2040838 2011, Product analysis, DACO: 3.4.1, 3.4.2 CBI

2040839 2011, Chemical and physical properties, DACO: 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI

2040840 2011, Storage stability, DACO: 3.5.10 CBI

2040841 2011, Storage stability, DACO: 3.5.10 CBI

2040865 2011, Chemistry requirements for EP, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI

2040866 2011, Manufacturing process, DACO: 3.2.1, 3.2.2, 3.2.3 CBI

2040867 2011, Specifications, DACO: 3.3.1, 3.3.2 CBI

2040869 2011, Product analysis, DACO: 3.4.1, 3.4.2 CBI

2040870 2011, Chemical and physical properties, DACO: 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI

2040871 2011, Storage stability, DACO: 3.5.10 CBI

2040872 2011, Storage stability, DACO: 3.5.10 CBI

2.0 Human and Animal Health

PMRA Document Number	Reference
2040689	2011, Use Description, DACO 5.2
2040763	2011, Use Description, DACO 5.2
2086018	2011, Use Description, DACO 5.2
2086034	2011, Use Description, DACO 5.2
2086060	2011, Use Description, DACO 5.2

3.0 Environment

PMRA Document Number	Reference
1603999	2008, Acute Contact Toxicity Test with the Honey Bee (*Apis mellifera*), DACO: 9.2.4.1
1604000	2008, Dehydrated Garlic Powder - Acute Contact Toxicity Test with the Honey Bee, DACO: 9.2.4.1
1603998	2008, Dehydrated Garlic Powder. Final Report. *Daphnia magna* 48-hour Acute Toxicity Test, DACO: 9.1, 9.3.2
1604001	2008, Rainbow Trout (*Oncorhynchus mykiss*) 96-Hour Toxicity Test, DACO: 9.1, 9.5.2.1
1604002	2008, Dehydrated Garlic Powder. Final Report. Rainbow Trout (*Oncorhynchus mykiss*) 96-Hour Acute Toxicity Test, DACO: 9.1, 9.5.2.1
1604003	2008, Acute Oral Toxicity Test (LD_{50}) with Northern bobwhite quail (*Colinus virginianius*), DACO: 9.1, 9.6.2.1
1604004	2008, Dehydrated Garlic Powder - Acute Oral Toxicity Test (LD_{50}) with Northern bobwhite quail (*Colinus virginianus*), DACO: 9.1, 9.6.2.1
1604006	2008, Dehydrated Garlic Powder - Dietary Toxicity Test (LC_{50}) with Northern Bobwhite (*Colinus virginianus*), DACO: 9.1, 9.6.2.4

4.0 Value

PMRA Document Number	Reference
2040694	2011. Value summary. DACO: 10.1
2040699	2011. Mode of action. DACO: 10.2.1
2040700	2011. Desciption of pest problem. DACO: 10.2.2
2040723	2011. Laboratory study. DACO: 10.2.3.2
2040708	2011. Trial report powdery mildew grapevines. DACO: 10.2.3.3
2040709	2011. Trial report powdery mildew grapevines. DACO: 10.2.3.3
2040710	2011. Trial report powdery mildew grapevines. DACO: 10.2.3.3
2040711	2011. Trial report apple scab. DACO: 10.2.3.3
2040712	2011. Trial report apple scab. DACO: 10.2.3.3
2040713	2011. Trial report apple scab. DACO: 10.2.3.3
2040714	2011. Trial report apple scab. DACO: 10.2.3.3
2040716	2011. Trial report apple scab. DACO: 10.2.3.3
2040720	2011. Summary trial reports. DACO: 10.2.3.3
2040722	2011. Non safety adverse effects. DACO: 10.3.1

B. Additional Information Considered

i) Published Information

1.0 Environment

PMRA Document Number	Reference
2197494	2009, Allyl sulfides, Hazardous Substances Data Bank, DACO: 9.9